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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,946	03/24/2000	Frank R. Ruderman	MBHB00-203	1964

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EXAMINER
BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/534,946	RUDERMAN ET AL.
	Examiner	Art Unit
	Carolyn M Bleck	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-28 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-28 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 10 July 2003. Claims 21 and 35 have been canceled. Claim 36 is newly added. Claims 22-27 have been amended.

Specification

2. The objections to the specification relating to the abstract and trademark issues are hereby withdrawn due to the amendment filed 10 July 2003.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 22, 24-28, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) in view of the Applicant's admission in the background of the art of the present application (09/534,946).

(A) As per claim 36, Levin discloses a system for managing coronary disease data (reads on "managing cardiovascular healthcare information") (col. 1 lines 9-18, col. 2 lines 39-45 and 50-57, and col. 11 lines 12-15) comprising:

(a) a centralized data management center for maintaining a record of data received by and transmitted from relational databases relating to coronary disease data, wherein the records include patient diagnosis and treatment information collected over time, wherein the processing means at the centralized data management center provide for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, such as analyzing ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (Fig. 3 and 25A, col. 5 lines 1-36, col. 6 lines 3-28, col. 7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10), wherein the processing means runs a lipid classification algorithm by inputting patient's LDL and HDL cholesterol values and checking the patient values against the upper limit for normal LDL and HDL cholesterol values, wherein the normal values are stored in the databases at the centralized data management center (Fig. 1-2, 4, and 11-15, Abstract lines 11-14, col. 5 lines 25-37, col. 8 line 21 to col. 9 line 40, col. 10 lines 56-57, and col. 11 lines 5-10);

(b) a monitor displaying a menu (reads on "data entry interface") for entering all known and required information, including patient information such as name, birth date, sex, height, and weight, and test results, such as lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and storing the information and test results at the

centralized data management center databases (Abstract lines 11-14, Fig. 1-2, col. 4 line 53 to col. 5 line 36, col. 10 lines 50-57, and col. 11 lines 5-10); and

(c) processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, such as ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (reads on "diagnostic engine") (col. 7 lines 55-63, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10), wherein the algorithm correlates test results with risk factors for coronary artery disease and possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15), wherein an example of the correlation of risk factors includes running a classification of a patient into either an HDL cholesterol acceptable class or a HDL cholesterol low class or HDL elevated class (Fig. 25A-B and col. 8 lines 20-60).

In addition, Levin includes within Figures 11-15 measuring HDL and LDL levels using the units of mg/DL and then classifying the patient into an appropriate class, either an elevated class or optimal class based on the HDL and LDL levels (col. 8 lines 21-47). It is noted that HDL and LDL levels are sub classes of a patient's total cholesterol (Fig. 11-15 and col. 8 lines 21-47).

However, if Levin's HDL and LDL levels are not considered to be "an amount of LDL and LDL subclass particles" by Applicant as recited in claim 36, Applicant's

background of the art (see page 1 lines 15-24 of application 09/534,946) includes that "the art describes cardiovascular risk factors such as age, smoking, weight, family history, blood pressure, lipid profiles including low density lipoprotein (LDL) and high density lipoprotein (HDL) and subclasses (fractions) of LDL and HDL, and methods for measuring these factors and relating them to treatment are known (emphasis added)."

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned measurement data disclosed in the Applicant's background of the art within the system taught by Levin with the motivation of accurately diagnosing a patient with coronary artery disease by using a comprehensive set of data thus allowing a physician to effectively manage coronary artery disease (Levin; col. 2 lines 15-60).

(B) As per claim 22, Levin discloses a monitor displaying a menu (reads on "physician data access interface") for providing a physician, such as a cardiologist, with the ability to access, display, review, and transfer information stored at the centralized data management center (col. 2 lines 1-15, col. 5 lines 49-67, and col. 11 lines 1-10).

(C) As per claim 24, Levin discloses a storage means that stores information related to coronary illness risk factors which have been established based on empirical data, wherein the information allows physicians to determine the effectiveness of diagnoses and treatments as the information is gathered over time and as the pool of treated patients increases (Abstract lines 11-14, col. 6 line 3-15, and col. 10 lines 3-15). It is

respectfully submitted that the storage means disclosed by Levin is a form of a knowledge base as the data collected in the database is a collection of knowledge of specialists such as cardiologists, and the data collected will be used to effectively identify patients at significant risk of sudden death and to quantify the success of various treatments both for the patient pool and fro particular patients (col. 6 line 3-15).

(D) As per claims 25-27, Levin discloses processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, wherein patient test results include ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient, and wherein the test results determine base numbers for a patient (reads on "diagnostic engine" and "baseline determination for ongoing therapy monitoring") (Fig. 3, col. 5 lines 25-36, col. 6 lines 16-28, col. 7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 9 lines 18-39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10) wherein:

(a) the algorithms correlate test results with possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15);

(b) the algorithms correlate test results with possible or recommended diagnoses, such as such as whether the levels of total cholesterol, LDL cholesterol, and HDL cholesterol are acceptable or not, and the diagnosis classification for blood

pressure of a patient, wherein the classification includes normal, high-normal, mild hypertension, moderate hypertension, severe hypertension, and very severe hypertension (col. 8 line 21 to col. 9 line 39, col. 10 lines 3-15, and col. 11 line 10-15); and

(c) the algorithms correlate diagnosis information with possible or recommended treatments (Fig. 25A-B, col. 5 lines 16-37, col. 6 line 16 to col. 7 line 47, col. 8 line 21 to col. 9 line 39, and col. 10 lines 3-15).

(E) As per claim 28, Levin discloses the algorithms correlating test results with possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy (reads on "personalized drugs"), diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15).

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) and the Applicant's admission in the background of the art of the present application (09/534,946) as applied to claim 21, and further in view of Surwit et al. (6,024,699).

(A) As per claim 23, the relevant teachings of Levin and the Applicant's admission in the background of the art of the present application (09/534,946), and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Levin and the Applicant's background of the art fail to expressly disclose a communication system allowing the physician to communicate cardiovascular healthcare management information to a patient. However, Levin includes communicating coronary illness information to and from a physician, such as a cardiologist, via communication network (Fig. 1-3 and 25A-25B, col. 2 line 62 to col. 3 line 10, col. 4 lines 31-55, col. 7 lines 33-47, and col. 7 line 64 to col. 8 line 7).

Surwit discloses a system for monitoring, diagnosing, prioritizing, and treating chronic medical conditions of a plurality of remotely located patients, wherein treatment information is provided to a patient via a computer network (Fig. 1 and 3, col. 2 lines 38-55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned component of Surwit within the system taught collectively by Levin and Applicant's background of the art with the motivation of quickly and easily monitoring patients and automatically identifying a patient with a medical condition, quickly preparing and revising medicine dosages for a patient and then efficiently communicating revised dosage information to a patient (Surwit; col. 2 lines 25-35), and reducing the costs of medical treatment by providing a fast, effective technique for providing comprehensive management of coronary patients based on risk factors including up to date diagnoses and treatment information (Levin; col. 2 lines 16-49).

6. Claims 22, 24-28, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) in view of Otvos (6,576,471).

(A) As per claim 36, Levin discloses a system for managing coronary disease data (reads on "managing cardiovascular healthcare information") (col. 1 lines 9-18, col. 2 lines 39-45 and 50-57, and col. 11 lines 12-15) comprising:

(a) a centralized data management center for maintaining a record of data received by and transmitted from relational databases relating to coronary disease data, wherein the records include patient diagnosis and treatment information collected over time, wherein the processing means at the centralized data management center provide for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, such as analyzing ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (Fig. 3 and 25A, col. 5 lines 1-36, col. 6 lines 3-28, col. 7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10), wherein the processing means runs a lipid classification algorithm by inputting patient's LDL and HDL cholesterol values and checking the patient values against the upper limit for normal LDL and HDL cholesterol values, wherein the normal values are stored in the databases at the centralized data management center (Fig. 1-2, 4, and 11-15, Abstract lines 11-14, col. 5 lines 25-37, col. 8 line 21 to col. 9 line 40, col. 10 lines 56-57, and col. 11 lines 5-10);

(b) a monitor displaying a menu (reads on "data entry interface") for entering all known and required information, including patient information such as name, birth date, sex, height, and weight, and test results, such as lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and storing the information and test results at the centralized data management center databases (Abstract lines 11-14, Fig. 1-2, col. 4 line 53 to col. 5 line 36, col. 10 lines 50-57, and col. 11 lines 5-10); and

(c) processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, such as ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (reads on "diagnostic engine") (col. 7 lines 55-63, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10), wherein the algorithm correlates test results with risk factors for coronary artery disease and possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15), wherein an example of the correlation of risk factors includes running a classification of a patient into either an HDL cholesterol acceptable class or a HDL cholesterol low class or HDL elevated class (Fig. 25A-B and col. 8 lines 20-60).

In addition, Levin includes within Figures 11-15 measuring HDL and LDL levels using the units of mg/DL and then classifying the patient into an appropriate class, either an elevated class or optimal class based on the HDL and LDL levels (col. 8 lines

21-47). It is noted that HDL and LDL levels are sub classes of a patient's total cholesterol (Fig. 11-15 and col. 8 lines 21-47).

However, if Levin's HDL and LDL levels are not considered to be "an amount of LDL and LDL subclass particles" by Applicant as recited in claim 36, Otvos discloses generating lipoprotein measurement values for a patient's blood sample, the lipoprotein measurement values including a plurality of lipoprotein subclass variable measurements, including LDL size, LDL concentration, large HDL concentration, and large VLDL concentration, comparing the plurality of patient lipoprotein subclass variable values with respective predetermined test criteria for determining whether the subclass variable values are associated with a higher or lower risk of developing coronary heart disease, evaluating the lipoprotein measurement values and generating a reduced target value or values for what represents an optimal or low risk value for selected lipoprotein constituents to provide a patient-specific treatment guideline based on the presence of predetermined risk criteria, and automatically generating personalized lipoprotein-based reports for patients (col. 19 line 55 to col. 20 line 40).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned lipoprotein subclass variable measurements of Otvos within the system taught by Levin with the motivation of accurately diagnosing a patient with coronary artery disease by using a comprehensive set of data thus allowing a physician to effectively manage coronary artery disease (Levin; col. 2 lines 15-60) and utilizing subclass information for lipoproteins because

subclass information provides a more reliable indicator of a patient's risk to develop coronary heart disease (Otvos; col. 1 lines 55-65).

(B) As per claim 22, Levin discloses a monitor displaying a menu (reads on "physician data access interface") for providing a physician, such as a cardiologist, with the ability to access, display, review, and transfer information stored at the centralized data management center (col. 2 lines 1-15, col. 5 lines 49-67, and col. 11 lines 1-10).

(C) As per claim 24, Levin discloses a storage means that stores information related to coronary illness risk factors which have been established based on empirical data, wherein the information allows physicians to determine the effectiveness of diagnoses and treatments as the information is gathered over time and as the pool of treated patients increases (Abstract lines 11-14, col. 6 line 3-15, and col. 10 lines 3-15). It is respectfully submitted that the storage means disclosed by Levin is a form of a knowledge base as the data collected in the database is a collection of knowledge of specialists such as cardiologists, and the data collected will be used to effectively identify patients at significant risk of sudden death and to quantify the success of various treatments both for the patient pool and fro particular patients (col. 6 line 3-15).

(D) As per claims 25-27, Levin discloses processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, wherein patient test results include ECG information,

lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient, and wherein the test results determine base numbers for a patient (reads on "diagnostic engine" and "baseline determination for ongoing therapy monitoring") (Fig. 3, col. 5 lines 25-36, col. 6 lines 16-28, col. 7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 9 lines 18-39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10) wherein:

(a) the algorithms correlate test results with possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15);

(b) the algorithms correlate test results with possible or recommended diagnoses, such as such as whether the levels of total cholesterol, LDL cholesterol, and HDL cholesterol are acceptable or not, and the diagnosis classification for blood pressure of a patient, wherein the classification includes normal, high-normal, mild hypertension, moderate hypertension, severe hypertension, and very severe hypertension (col. 8 line 21 to col. 9 line 39, col. 10 lines 3-15, and col. 11 line 10-15); and

(c) the algorithms correlate diagnosis information with possible or recommended treatments (Fig. 25A-B, col. 5 lines 16-37, col. 6 line 16 to col. 7 line 47, col. 8 line 21 to col. 9 line 39, and col. 10 lines 3-15).

(E) As per claim 28, Levin discloses the algorithms correlating test results with possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy (reads on "personalized drugs"), diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15).

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) and Otvos (6,576,471) as applied to claim 21, and further in view of Surwit et al. (6,024,699).

(A) As per claim 23, the relevant teachings of Levin and Otvos, and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Levin and Otvos fail to expressly disclose a communication system allowing the physician to communicate cardiovascular healthcare management information to a patient. However, Levin includes communicating coronary illness information to and from a physician, such as a cardiologist, via communication network (Fig. 1-3 and 25A-25B, col. 2 line 62 to col. 3 line 10, col. 4 lines 31-55, col. 7 lines 33-47, and col. 7 line 64 to col. 8 line 7).

Surwit discloses a system for monitoring, diagnosing, prioritizing, and treating chronic medical conditions of a plurality of remotely located patients, wherein treatment information is provided to a patient via a computer network (Fig. 1 and 3, col. 2 lines 38-

55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned component of Surwit within the system taught collectively by Levin and Otvos with the motivation of quickly and easily monitoring patients and automatically identifying a patient with a medical condition, quickly preparing and revising medicine dosages for a patient and then efficiently communicating revised dosage information to a patient (Surwit; col. 2 lines 25-35), and reducing the costs of medical treatment by providing a fast, effective technique for providing comprehensive management of coronary patients based on risk factors including up to date diagnoses and treatment information (Levin; col. 2 lines 16-49).

Response to Arguments

8. Applicant's arguments with respect to claims 22-28 and 36 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 10 July 2003.

(A) At pages 2-4 of the response filed 10 July 2003, Applicant argues that the prior art simply does not describe Applicant's cardiovascular healthcare system based on amounts of LDL and HDL subclass particles.

In response, all of the limitation which Applicant disputes as missing in the applied references, include the features newly added in the 10 July 2003 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Levin, the Applicant's background of the art, Otvos, and/or Surwit, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (see paper numbers 7 and 10), and incorporated herein.

In response, the Examiner respectfully submits that each limitation recited in claims 22-28 and 36 has been addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Levin, the Applicant's background of the art, Otvos, and/or Surwit based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as clearly detailed in the remarks and explanations given above and in the previous Office Action (paper numbers 7 and 10), and incorporated herein.

As such, it is respectfully submitted that Applicant appears to view the applied references in a vacuum without considering the knowledge of average skill in the art.

In addition, the Examiner is concerned that, aside from merely alleging that certain claimed features are not obvious from Levin, the Applicant's background of the

art, Otvos, and/or Surwit, essentially in the form of blanket statements, Applicant does not point to any specific distinction(s) between the features disclosed in the references and the features that are presently claimed. In particular, 37 CFR 1.111(b) states, "A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference does not comply with the requirements of this section." Applicant has failed to specifically point out **HOW** the language of the claims patentably distinguishes them from the applied references. Also, arguments or conclusions of Attorney cannot take the place of evidence. *In re Cole*, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); *In re Schulze*, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); *Mertizner v. Mindick*, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a low density lipoprotein fraction assay for cardiac disease risk (5,925,229), a method for analyzing a patient's risk of coronary heart disease by determining the presence of NMR-derived or based lipoprotein constituent value abnormalities (US 2002/0087276), and method for providing personalized lipoprotein-based risk assessments (US 2003/0119194).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-

3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

12. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306	[Official communications; including After Final communications labeled "Box AF"]
(703) 746-8374	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
August 21, 2003

ALEXANDER KALINOWSKI
PATENT EXAMINER
AU 3626